

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

NOVARTIS PHARMACEUTICALS, CORP. et
al.,

Plaintiffs,

v.

WOCKHARDT USA LLC and WOCKHARDT
LIMITED,

Defendants.

NOVARTIS PHARMACEUTICALS, CORP. et
al.,

Plaintiffs,

v.

SUN PHARMA GLOBAL FZE, et al.,

Defendants.

NOVARTIS PHARMACEUTICALS, CORP. et
al.,

Plaintiffs,

v.

ACTAVIS LLC, et al.,

Defendants.

Civil Action No. 12-3967
(SDW) (MCA)

(Consolidated with Civil Action
Nos. 12-4393, 13-1028, and 13-
2379)

OPINION

September 3, 2013

NOVARTIS PHARMACEUTICALS, CORP. et
al.,

Plaintiffs,

v.

ACCORD HEALTHCARE INC., et al.,

Defendants.

WIGENTON, District Judge.

Before the Court is Wockhardt USA LLC and Wockhardt Limited's (collectively "Wockhardt") Appeal from United States Magistrate Judge Madeline C. Arleo's ("Magistrate Judge Arleo") May 31, 2013 Order granting Plaintiffs' Novartis Pharmaceuticals Corporation, Novartis Corporation, and Novartis AG ("Plaintiffs") request for leave to amend the Disclosure of Asserted Claims pursuant to Federal Rule of Civil Procedure 72 and Local Civil Rule 72.1(c)(1). This Court, having considered the parties' submissions, decides this matter without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons stated below, Wockhardt's appeal is **DENIED**.

BACKGROUND

As Magistrate Judge Arleo provided the relevant facts on the record at the May 21, 2013 hearing, this Court will only provide the more recent background. (See Dkt. 78, Hr'g Tr. 21:3-27:2, May 21, 2013.) On May 31, 2013, Magistrate Judge Arleo issued an Order granting Plaintiffs' request to amend the Disclosure of Asserted Claims. On June 7, 2013, Wockhardt filed the instant appeal of Magistrate Judge Arleo's decision. On June 24, 2013, Plaintiffs filed their opposition and Wockhardt filed its reply on July 8, 2013.

LEGAL STANDARD

A magistrate judge may hear and determine any non-dispositive pretrial matter pending before the district court pursuant to 28 U.S.C. § 636(b)(1)(A). The district court will only reverse a magistrate judge's decision on these matters if it is "clearly erroneous or contrary to law." 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a); L. Civ. R. 72.1(c)(1)(A). "This Court will review a magistrate judge's findings of fact for clear error." Lithuanian Commerce Corp. v. Sara Lee Hosiery, 177 F.R.D. 205, 213 (D.N.J. 1997) (citing Lo Bosco v. Kure Eng'g Ltd., 891 F. Supp. 1035, 1037 (D.N.J. 1995)).

A ruling is "clearly erroneous" if "although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." United States v. United States Gypsum Co., 333 U.S. 364, 395 (1948). A decision is considered contrary to law if the magistrate judge has "misinterpreted or misapplied applicable law." Doe v. Hartford Life Acc. Ins. Co., 237 F.R.D. 545, 548 (D.N.J. 2006).

The district court "will not reverse the magistrate judge's determination, even if the court might have decided the matter differently." Bowen v. Parking Auth. of City of Camden, No. 00-5765, 2002 WL 1754493, at *3 (D.N.J. July 30, 2002). Furthermore, "[a] district judge's simple disagreement with the magistrate judge's findings is insufficient to meet the clearly erroneous standard of review." Andrews v. Goodyear Tire & Rubber Co., 191 F.R.D. 59, 68 (D.N.J. 2000).

As the Federal Circuit has guided, "[d]ecisions enforcing local rules in patent cases will be affirmed unless clearly unreasonable, arbitrary, or fanciful; based on erroneous conclusions of law; clearly erroneous; or unsupported by any evidence." O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc., 467 F.3d 1355, 1366-67 (Fed. Cir. 2006) (citing Genentech, Inc. v. Amgen, Inc., 289 F.3d 761, 774 (Fed. Cir. 2002)).

DISCUSSION

Pursuant to Local Patent Rule 3.7, leave to amend disclosures may be granted “by order of the Court upon a timely application and showing of good cause.” L. Pat. R. 3.7. In particular, a party may amend its invalidity contentions or disclosures upon establishing three requirements: “(1) the moving party makes a timely application to the court; (2) there is good cause for the amendment; and (3) there is no undue prejudice to the adverse party.” AstraZeneca AB v. Hanmi, USA, Inc., No. 11-760, 2013 WL 264609, at *1 (D.N.J. Jan. 23, 2013). Unlike the liberal standard for amending pleadings, “the philosophy behind amending claim charts is decidedly conservative, and designed to prevent the ‘shifting sands’ approach to claim construction.” King Pharms., Inc. v. Sandoz, Inc., No. 08-5974, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010) (citing Atmel Corp. v. Info. Storage Devices, Inc., No. 95-1987, 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998)).

Analysis

In reviewing the record, this Court notes at the outset that there arguably are several reasons to deny Plaintiffs’ request to amend its disclosure of asserted claims in this matter. In fact, if presented with the parties’ arguments in the first instance, this Court may have been inclined to deny the request to amend. However, the standard of review here is not whether this Court disagrees with Magistrate Judge Arleo’s ultimate decision; it is whether the decision is clearly erroneous or contrary to law. See Jazz Pharms., Inc. v. Roxane Labs., Inc., No. 10-6108, 2013 WL 785067, at *4 (D.N.J. Feb. 28, 2013) (“In short, mere disagreement with the judicial finding of a Magistrate Judge does not meet the ‘clear error’ standard required for reversal.”); see also Bowen, 2002 WL 1754493, at *3, Andrews, 191 F.R.D. at 68. After carefully dissecting the

record and the parties' arguments, this Court finds that Magistrate Judge Arleo's decision is neither clearly erroneous nor contrary to law.

A. Good cause

The crux of this appeal focuses on the requirement of good cause. To establish good cause, parties must "proceed with diligence in amending [their] contentions when new information comes to light in the course of discovery." O2 Micro, 467 F.3d at 1366. The moving party has the burden of demonstrating its diligence. Id. Furthermore, the moving party must show that it was both diligent throughout discovery and in "discovering the basis for the proposed amendment." West v. Jewelry Innovations, Inc., No. 07-1812, 2008 WL 4532558, at *2 (N.D. Cal. Oct. 8, 2008).

Wockhardt presents several arguments relating to its contention that Magistrate Judge Arleo erroneously concluded that Plaintiffs had established good cause to amend its disclosures. First, Wockhardt argues that Magistrate Judge Arleo's finding of good cause was clearly erroneous in that it ignored this Court's previous findings. (Wockhardt Br. 6-7.) Specifically, Wockhardt points to this Court's comments in connection with a Temporary Restraining Order ("TRO") hearing held on March 1, 2013. (See Dkt. No. 53-16, TRO Hr'g Tr. 76:23-77:3, March 1, 2013.) Next, Wockhardt argues that Magistrate Judge Arleo's finding of good cause was not supported by the record. (Wockhardt Br. 7-8.) In support of this argument, Wockhardt asserts that at the time the local disclosures were filed, Plaintiffs were aware that the U.S. Patent No. 8,324,189 ("the '189 Patent") would issue but nevertheless made a strategic litigation decision to not pursue any claims regarding the U.S. Patent No. 8,052,987 ("the '987 Patent"). (Id. at 8.) Accordingly, Wockhardt claims that the "Magistrate's findings cannot be reconciled with the record." (Id.)

Wockhardt further argues that Magistrate Judge Arleo's finding of good cause was clearly erroneous because it ignored that no patent rights regarding Plaintiffs' ability to assert the '987 Patent have changed. (Id.) In addition, Wockhardt contends that Magistrate Judge Arleo's finding of good cause was contrary to the Local Patent Rules. (Id. at 10.) Wockhardt argues that the finding that "a change in business strategy" constitutes good cause is not cited in any case law and is contrary to law. (Id.)

In response, Plaintiffs contend that Wockhardt misconstrues the purpose of the good cause standard for amending disclosures in the Local Patent Rules. (Pls. Opp. 6-7.) According to Plaintiffs, rather than conveying substantive patent rights, the "standard [] allows the Court to balance a party's interest in having its dispute resolved on the merits against the Court's interest in efficient case management." (Id. at 8.) Plaintiffs argue that Wockhardt ignores Magistrate Judge Arleo's discussion regarding the consolidation of this action with the pending 2013 case and focuses only on the ruling pertaining to the issuance of the '189 Patent. (Id.)

Moreover, Plaintiffs argue that Magistrate Judge Arleo concluded that the issuance of the '189 Patent gave rise to "changed circumstances" which appropriately fell within the realm of "good cause" as intended by the Local Patent Rules. (Id. at 9.) Additionally, Plaintiffs argue that despite Wockhardt's contention that the '189 Patent would inevitably issue, the process was not "automatic" and took longer than anticipated. (Id. at 11-12.) Plaintiffs also highlight the complementary nature of the '189 and '987 Patents and the change in Plaintiffs' legal rights over zoledronic acid with the '189 Patent issuance. (Id. at 12-13.)

This Court finds that Magistrate Judge Arleo's finding of good cause was not clearly erroneous. First, Wockhardt's reliance on this Court's comments during the TRO hearing is misplaced. (See Wockhardt Br. 6-7; Wockhardt Reply 2-3, 6.) The TRO hearing involved a

request for extraordinary relief and the circumstances in which this Court made comments relating to the parties' motives or actions do not constitute "findings" relevant to Plaintiffs' request to amend its disclosures.

Secondly, although Wockhardt focuses on Magistrate Judge Arleo's discussion regarding Plaintiffs' "change of business strategy" in connection with the good cause prong, it was not the only reason that was cited, as reflected in the record. In fact, Magistrate Judge Arleo articulated that "[t]he facts related to the patent rights for Novartis have changed significantly and this change occurred less than three months ago after Novartis had served its disclosure of asserted claims back in October of 2012." (Dkt. 78, Hr'g Tr. 22:17-21.) Moreover, Magistrate Judge Arleo noted Plaintiffs' argument that "the [']189 and [']987 [Patents] are inextricably linked in terms of whether it makes sense from the litigation perspective as well as a business perspective to pursue the [']987 [Patent] against Wockhardt." (Dkt. 78, Hr'g Tr. 23:4-7.) Accordingly, until the '189 Patent was actually issued, Plaintiffs' rights relating to the uses for products covered by the '987 Patent were technically uncertain. As Magistrate Judge Arleo stated, there was a gap between the issuance of the '189 Patent in December 2012 and Plaintiffs' request to gain Wockhardt's consent to amend its disclosures in early February 2013. (Dkt. 78, Hr'g Tr. 24:22-25:1.) This Court agrees with Magistrate Judge Arleo that this gap in time was minimal and does not demonstrate Plaintiffs' lack of diligence in requesting to amend its disclosures.

Furthermore, although Wockhardt argues that Magistrate Judge Arleo's ruling is contrary to law, Wockhardt cites no law in support of this proposition. Particularly, as Plaintiffs note, Wockhardt does not cite to any case holding that a change in legal rights—such as the instant circumstances—would not constitute good cause for amending disclosures under the Local Patent Rules. Instead, the relevant case law guides that the Local Patent Rules are "not a

straightjacket into which litigants are locked from the moment their contentions are served[.],” and rather a “modest degree of flexibility [exists], at least near the outset.” TFH Publ’ns, Inc. v. Dorskocil Mfg. Co., Inc., 705 F. Supp. 2d. 361, 366 (D.N.J. 2010) (internal citations omitted). Notably, this case is in its infancy in that there have been no Markman hearings, depositions, experts, summary judgment motions, or a set trial date. Accordingly, this Court finds it appropriate to employ a “modest degree of flexibility” with respect to the requested amendment where good cause has been established. In finding that good cause existed, Magistrate Judge Arleo acknowledged that “it is a bit unusual and really I don’t find much support in this unique context and other cases.” (Dkt. 78, Hr’g Tr. 23:14-20; see Wockhardt Reply 8-9.) However, an unusual finding that arises in the context of novel circumstances does not amount to clear error or a ruling contrary to law.

B. Undue Prejudice

If the moving party is able to establish good cause, a court next considers whether there would be undue prejudice to the adverse party in allowing an amendment. L. Pat. R. 3.7; Jazz Pharms., Inc., 2013 WL 785067, at *5 (“Only if the moving party is able to show diligence may the court consider the prejudice to the non-moving party.”) An adverse party does not suffer undue prejudice merely because it is “operating under [the] original non-infringement contentions” and made “develop[ments] [in] strategies based on these contentions.” Hanmi, 2013 WL 264609, at *2. Furthermore, an adverse party is not prejudiced if an amendment results in “minor adjustment[s]” to the case schedule. Id.

Wockhardt argues that Magistrate Judge Arleo conflated the good cause and undue prejudice prongs and ignored the alleged prejudice to Wockhardt. (Wockhardt Br. 12-14.) Additionally, Wockhardt asserts that “[i]f changes in business strategy can generate good cause,

[business-based] harm caused by allowing an amendment, after the adverse party has relied on the binding litigation decisions of the moving party, should also support a finding of undue prejudice.” (Id. at 13.)

This Court finds that Magistrate Judge Arleo did not err in concluding that Wockhardt would not suffer undue prejudice as a result of granting Plaintiffs’ request to amend its disclosures. Magistrate Judge Arleo properly considered whether Wockhardt would suffer litigation prejudice, as contemplated by the Local Patent Rules. Magistrate Judge Arleo’s analysis of undue prejudice was not conflated with the “good cause” requirement. For instance, Magistrate Judge Arleo stated that the “second issue” to be examined is whether there was any “litigation prejudice” to consider. (Dkt. 78, Hr’g Tr. 24:7-10.) Magistrate Judge Arleo concluded, “I can’t see any aspect of trial prep[aration] that would be compromised,” especially in light of her inclination to consolidate the related, pending case. (Dkt. 78, Hr’g Tr. 24:7-12.) She further reasoned that “[t]he case is in its early stages . . . [as] [t]here’s been no Markman, [] no depositions, no experts, no summary judgment motions, no trial any time this year.” (Dkt. 78, Hr’g Tr. 24:13-16.) Finally, Magistrate Judge Arleo noted that “adding the claims of the [’]987 back to the consolidated case would not materially prejudice Wockhardt’s defense of this matter, which is really what the patent rules talk about in terms of prejudice.”¹ (Dkt. 78, Hr’g Tr. 24:16-21.) Accordingly, Magistrate Judge Arleo’s analysis regarding undue prejudice was clear and independent from the “good cause” determination.

In addition, Wockhardt’s argument that the Magistrate Judge should have considered “business prejudice” that may result from granting the amendment is unsubstantiated. Wockhardt does not point to any case law in support of this contention. Instead, Wockhardt’s

¹ This Court agrees with Wockhardt that the issue of consolidation applies to the “undue prejudice” prong rather than the “good cause” analysis. (Wockhardt Reply 12.) Based on the record, Magistrate Judge Arleo properly considered the issue of consolidation in evaluating undue prejudice.

stance is similar to the argument that was rejected in Hanmi where the court found that “operating under [the] original non-infringement contentions” and “developing [] strategies based on these contentions” did not constitute undue prejudice. 2013 WL 264609, at *2 (internal quotations omitted). As Magistrate Judge Arleo correctly identified, the Local Patent Rules serve to ensure that parties are not prejudiced in effectively litigating their claims, not to engage in regulating patent rights of parties. See Local Patent Rules, Explanatory Notes for 2011 Amendments. Accordingly, this Court finds that Magistrate Judge Arleo’s ruling was not clearly erroneous or contrary to law.

CONCLUSION

For the reasons stated above, this Court concludes that Magistrate Judge Arleo’s Order is neither clearly erroneous nor contrary to law. Thus, Magistrate Judge Arleo’s Order is **AFFIRMED** and Wockhardt’s appeal is **DENIED**.

s/ Susan D. Wigenton
Susan D. Wigenton, U.S.D.J.

cc: Madeline Cox Arleo, U.S.M.J.